



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Drive, Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5454
FAX: (410) 779-5707

June 17, 2010

BY FACSIMILE &
CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. J. Chris Hrouda
Executive Vice President
Biomedical Services
American National Red Cross
2025 E Street, N.W
Washington, D.C. 20006

RE: *United States v. American National Red Cross*, Civil Action No. 93-0949 (JGP)

Dear Mr. Hrouda:

On October 30, 2009, the Food and Drug Administration (FDA) issued the American National Red Cross (ARC) an Adverse Determination Letter (ADL) under Paragraph X.A. of the Amended Consent Decree of Permanent Injunction (Decree) entered on April 15, 2003.

Paragraph X.A. provides the FDA with authority to assess a penalty for “each unit of *unsuitable blood or blood component*¹ that [the American Red Cross] (ARC) distributes after entry of [the Decree] for which FDA determines that the release was preventable by *ARC*....” Paragraph X.A.2. of the Decree provides that “[i]f FDA determines that use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote, FDA may assess a penalty up to \$5,000 for each such unit of *blood* or each such *blood component*. Notwithstanding the foregoing, FDA shall not assess *ARC* under this subparagraph (X.A.2) for the improper release of more than 100 units in any one event.”

FDA also stated in its October 30, 2009 ADL that we were continuing to evaluate assessment of fines and alternate or additional regulatory measures and that the decision on those matters would be communicated by FDA to ARC separately. The purpose of this letter is to notify ARC of FDA's decision. For your convenience, we are resending the list of recalls cited in the ADL, now including the penalty amounts assessed for each.

¹ The italics in the quotations from the Decree are in the original and indicate that the italicized word was defined in Paragraph III of the Decree.

In the October 30, 2009 ADL, FDA explained that its review of the database and files identified classified² recalls conducted by ARC that occurred from April 15, 2003, through September 30, 2008, and that the October 30, 2009 ADL did not include any classified recalls previously identified in the May 16, 2005, September 7, 2006, or February 6, 2008 ADLs. FDA also explained that only those recall events classified by FDA as of September 30, 2008 were included in the October 30, 2009 ADL; that the ADL did not necessarily include all events that occurred during the specified time period; and that after further FDA review, additional recall events may be identified that occurred during the aforementioned time period but are not included in the October 30, 2009 ADL or previous ADLs.

FDA has incorporated ARC's concerns with some of the recall events discussed on Bates page 088904 of its November 19, 2009 letter. As such, FDA has identified 230 events in which ARC reported to FDA that it retrieved unsuitable blood components. The unsuitable blood components are listed by event in the attachment to this letter. The events are identified by ARC-assigned biological product deviation number or Problem Report Number and FDA-assigned recall numbers and are arranged by ARC region. FDA determined that all of these events were preventable by ARC, that they all meet the health hazard criteria of Paragraph X.A.2. of the Decree, and that no penalty exception listed in Paragraph X.B. of the Decree applies. These events involved a total of 7,359 unsuitable blood components. However, thirteen of the recall events involved distribution of more than 100 unsuitable blood components but were limited for penalty purposes to 100 units per event as provided by Paragraph X.A.2. of the Decree. Thus, the total number of unsuitable blood components for which FDA is assessing a penalty under Paragraph X.A.2. of the Decree is 2,096.

Paragraph X.A.2. of the Decree sets forth three non-exhaustive factors FDA considers when determining whether to assess a penalty and the amount of a penalty: "(1) the potential effect of the event on the public health, e.g., the number and seriousness of exposures; (2) *ARC's* trends with respect to the same or similar events involving the release of unsuitable products; and (3) the degree to which *ARC* contributed to the improper release of the *blood* or *blood components*." FDA has considered these factors and has assessed penalties accordingly for each unsuitable blood component (see attached list). Some of the individual penalty amounts are higher than penalties assessed for similar events in earlier ADLs. FDA believes this adjustment is warranted based on the cumulative numbers of such events under the second factor. The total penalty being assessed under Paragraph X.A.2 is \$9,776,000.00.

Paragraph IX.F.5 of the Decree states that "All penalties assessed under this Order shall be based on the year in which the violative conduct occurred. The annual cap amounts described in paragraph IX.F.1 of this Order shall also be attributed solely to the year in which the violative conduct occurred." The penalty period described in this letter includes violations that occurred in 2003 through 2008. The penalty amounts assessed as a result of the violations for each of those years is \$525,000 in 2003, \$2,302,000 in 2004, \$2,019,000 in 2005, \$3,122,000 in 2006, \$1,728,000 in 2007 and \$80,000 in 2008.

The total fine that FDA is imposing is \$9,776,000. Payment of that amount is due no later than thirty days from the date of receipt of this letter.

In accordance with paragraph IX.F.7. of the Decree, we are attaching instructions for the electronic transfer of this payment to the United States Treasury. ARC must, contemporaneous with the electronic

² Recall classifications are numerical designations assigned by FDA to indicate the relative degree of health hazard presented by the recalled product. 21 CFR § 7.3(m).

Page 3 – Mr. J. Chris Hrouda

transfer, provide written notification to the FDA Director, Baltimore District and the Associate Commissioner of Regulatory Affairs that payment has been made.

If you have any questions regarding this response, please contact Nancy Rose, Compliance Officer, at (410) 779-5415, or Linda Mattingly, Consumer Safety Officer, at (410) 779-5443.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'E. Bonnin', is positioned above the printed name.

Evelyn Bonnin
Director, Baltimore District

Enclosures

cc: Ms. Gail McGovern
President and CEO
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006

Eva Quinley
Senior Vice President for Quality
and Regulatory Affairs
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006

Mary Elcano
General Counsel
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006

Bonnie McElveen-Hunter
Chairman, Board of Governors
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006

AMERICAN RED CROSS: Certain Class II recalls for the period April 15, 2003 through September 30, 2008

This chart does not include any classified recalls previously identified in the May 16, 2005, September 7, 2006 or February 6, 2008 Adverse Determination Letters (ADLs). Furthermore, this chart includes only those events classified by FDA as of September 30, 2008, and therefore does not necessarily include all events that occurred during the specified time period. After FDA review, additional penalties may be assessed for events that occurred during the aforementioned time period but that are not included in this or previous ADLs. FDA did not classify any recalls that met the requirements for penalties under Paragraph X of the Decree for the following regions:

Appalachian Region, FDA Registration 1173010
 Arizona Region, FDA Registration 2072997
 Midwest Region, FDA Registration 1973037
 Missouri-Illinois Region, FDA Registration 1973035
 New York-Penn Region, FDA Registration 2438445
 Pacific Northwest Region, FDA Registration 3072996
 River Valley Region, FDA Registration 1073003
 Western Lake Erie Region, FDA Registration 1573020

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|---------------------|--|---------------|---|--|--|-------------------------|
| Alabama/ 1073001 | (b) (4) | B-0711-08 | 1 – Red Blood Cells | Collection (inadequate arm prep; sterility may have been compromised) | \$5,000 | \$250,000 |
| | | B-0712-08 | 43 – Red Blood Cells Leukocytes Reduced | | | |
| | | B-0713-08 | 1 – Red Blood Cells Leukocytes Reduced Irradiated | | | |
| | | B-0714-08 | 5 – Fresh Frozen Plasma | | | |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|---------------------|--|---------------|--|---|--|-------------------------|
| Alabama/ 1073001 | (b) (4) | B-1800-08 | 633 – Red Blood Cells Leukocytes Reduced | Collection (inadequate arm prep; sterility may have been compromised) | \$5,000 for each of 100 blood components | \$500,000 |
| | | B-1801-08 | 19 – Fresh Frozen Plasma | | | |
| | | B-1802-08 | 5- Red Blood Cells Leukocytes Reduced Irradiated | | | |
| | | B-1803-08 | 2 – Red Blood Cells | | | |
| | | B-1804-08 | 37 – Plasma Frozen | | | |
| Alabama/ 1073001 | (b) (4) | B-1911-08 | 2 – Red Blood Cells (Apheresis) Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect Blood Donation Record (BDR) gender-specific questions were answered) | \$5,000 | \$10,000 |
| Alabama/ 1073001 | (b) (4) | B-1947-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |
| | | B-1948-08 | 1 – Red Blood Cells Leukocytes Reduced Irradiated | | | |
| Alabama/ 1073001 | (b) (4) | B-1951-08 | 1 - Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Alabama/ 1073001 | (b) (4) | B-1979-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|----------------------------|--|---------------|---|--|--|-------------------------|
| Badger Hawkeye/ 2173028 | (b) (4) | B-1434-07 | 166 – Platelets Pheresis Leukocytes Reduced | Quality control and distribution (inappropriate release of platelet components with unacceptable quality control) | \$4,000 for each of 100 blood components | \$400,000 |
| | | B-1435-07 | 16 – Platelets Pheresis Leukocytes Reduced Irradiated | | | |
| | | B-1436-07 | 4 – Platelets Pheresis Leukocytes Reduced Washed | | | |
| Badger Hawkeye/ 2173028 | (b) (4) | B-1141-08 | 53 – Platelets Leukocytes Reduced | Labeling (failure to properly label platelet products ‘Donor took aspirin’) | \$4,000 | \$212,000 |
| Badger Hawkeye/ 2173028 | (b) (4) | B-1416-08 | 1 – Fresh Frozen Plasma Pheresis | Donor eligibility (failure to defer two donors when an obsolete version of a reference for tattoos was utilized) | \$4,000 | \$12,000 |
| | | B-1417-08 | 1 – Platelets Pheresis Leukocytes Reduced Irradiated | | | |
| | | B-1418-08 | 1 – Platelets Pheresis Leukocytes Reduced | | | |
| Badger Hawkeye/ 2173028 | (b) (4) | B-1464-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel in a Creutzfeldt Jakob Disease (CJD) risk area) | \$4,000 | \$12,000 |
| | | B-1465-08 | 1 - Platelets | | | |
| | | B-1466-08 | 1 - Recovered Plasma | | | |
| Carolinas/ 1073007 | (b) (4) | B-0061-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|-----------------------|--|---------------|--|---|--|-------------------------|
| Carolinas/ 1073007 | (b) (4) | B-0063-08 | 1 – Fresh Frozen Plasma | Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered) | \$5,000 | \$20,000 |
| | | B-0064-08 | 2 – Red Blood Cells Leukocytes Reduced | | | |
| | | B-0065-08 | 1 – Plasma Frozen | | | |
| Carolinas/ 1073007 | (b) (4) | B-0069-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$5,000 |
| Carolinas/ 1073007 | (b) (4) | B-0076-08 | 2 – Fresh Frozen Plasma | Collection (inadequate arm prep; sterility may have been compromised) | \$5,000 | \$35,000 |
| | | B-0077-08 | 4 – Red Blood Cells Leukocytes Reduced | | | |
| | | B-0078-08 | 1 – Plasma Frozen | | | |
| Carolinas/ 1073007 | (b) (4) | B-0082-08 | 1 – Cryoprecipitated AHF | Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered) | \$5,000 | \$10,000 |
| | | B-0084-08 | 1 – Red Blood Cells Leukocytes Reduced | | | |
| Carolinas/ 1073007 | (b) (4) | B-0113-08 | 2 – Red Blood Cells (Apheresis) Leukocytes Reduced | Quality control and distribution (failure to perform quality control testing on product) | \$4,000 | \$8,000 |
| Carolinas/ 1073007 | (b) (4) | B-0135-08 | 16 – Red Blood Cells Leukocytes Reduced | Failure to control to control suspect blood component(s) (inappropriate release of blood components that should have been discarded for unacceptable shipping temperatures) | \$5,000 | \$80,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|-----------------------|--|---------------|---|---|--|-------------------------|
| Carolinas/ 1073007 | (b) (4) | B-0163-08 | 237 – Red Blood Cells Leukocytes Reduced | Testing (failure to perform syphilis testing properly) | \$5,000 for each of 100 blood components | \$500,000 |
| | | B-0164-08 | 26 – Red Blood Cells (Apheresis) Leukocytes Reduced | | | |
| | | B-0165-08 | 15 – Platelets Pheresis Leukocytes Reduced | | | |
| | | B-0166-08 | 73 – Fresh Frozen Plasma | | | |
| | | B-0167-08 | 27 – Cryoprecipitated AHF | | | |
| | | B-0168-08 | 16 – Plasma Cryoprecipitate Reduced | | | |
| Carolinas/ 1073007 | (b) (4) | B-0304-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |
| | | B-0305-08 | 1 – Plasma Frozen | | | |
| Carolinas/ 1073007 | (b) (4) | B-0319-08 | 2 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |
| Carolinas/ 1073007 | (b) (4) | B-0321-08 | 1 – Cryoprecipitated AHF | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$20,000 |
| | | B-0322-08 | 1 – Fresh Frozen Plasma | | | |
| | | B-0323-08 | 2 - Red Blood Cells Leukocytes Reduced | | | |
| Carolinas/ 1073007 | (b) (4) | B-0326-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Carolinas/ 1073007 | (b) (4) | B-0330-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Carolinas/ 1073007 | (b) (4) | B-0332-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Carolinas/ 1073007 | (b) (4) | B-0420-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$4,000 | \$4,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|-----------------------|--|---------------|--|---|--|-------------------------|
| Carolinas/ 1073007 | (b) (4) | B-0572-08 | 2 – Red Blood Cells (Apheresis) | Quality control and distribution (product did not meet specifications) | \$4,000 | \$8,000 |
| Carolinas/ 1073007 | (b) (4) | B-0693-08 | 1 – Red Blood Cells (Apheresis) Leukocytes Reduced | Component preparation (distribution of low volume unit) | \$4,000 | \$4,000 |
| Carolinas/ 1073007 | (b) (4) | B-0696-08 | 2 – Red Blood Cells (Apheresis) Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |
| Carolinas/ 1073007 | (b) (4) | B-0698-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Carolinas/ 1073007 | (b) (4) | B-0699-08 | 2 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$20,000 |
| | | B-0700-08 | 2 – Fresh Frozen Plasma | | | |
| Carolinas/ 1073007 | (b) (4) | B-0715-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for residence in a malarial risk area) | \$5,000 | \$5,000 |
| Carolinas/ 1073007 | (b) (4) | B-0728-08 | 2 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$10,000 |
| Carolinas/ 1073007 | (b) (4) | B-1088-08 | 1 – Fresh Frozen Plasma | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |
| | | B-1089-08 | 1 – Red Blood Cells Leukocytes Reduced | | | |
| Carolinas/ 1073007 | (b) (4) | B-1472-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Carolinas/ 1073007 | (b) (4) | B-1476-08 | 1 – Platelets Pheresis Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Carolinas/ 1073007 | (b) (4) | B-1480-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|---------------------------|--|---------------|--|---|--|-------------------------|
| Carolinas/ 1073007 | (b) (4) | B-1497-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$5,000 |
| Carolinas/ 1073007 | (b) (4) | B-1526-08 | 1 – Fresh Frozen Plasma | Failure to control suspect blood component(s) (inappropriate release after discovering clots in red blood cells) | \$5,000 | \$5,000 |
| Central Ohio/1573013 | (b) (4) | B-1999-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$5,000 |
| Central Plains/1973042 | (b) (4) | B-0417-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for receiving tattoo) | \$4,000 | \$8,000 |
| | | B-0418-08 | 1 – Recovered Plasma | | | |
| Connecticut/ 1273014 | (b) (4) | B-0277-7 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$10,000 |
| | | B-0278-7 | 1 – Platelets Leukocytes Reduced | | | |
| Connecticut/ 1273014 | (b) (4) | B-0538-7 | 1 – Red Blood Cells Leukocytes Reduced | Component preparation (product manufactured from an overweight unit of Whole Blood) | \$4,000 | \$4,000 |
| Connecticut/ 1273014 | (b) (4) | B-0694-07 | 4 – Red Blood Cells (Apheresis) Leukocytes Reduced | Component preparation (failure to perform required product quality control testing) | \$4,000 | \$16,000 |
| Connecticut/ 1273014 | (b) (4) | B-0845-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Connecticut/ 1273014 | (b) (4) | B-0924-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$10,000 |
| | | B-0925-08 | 1 – Platelets Leukocytes Reduced | | | |
| Connecticut/ 1273014 | (b) (4) | B-1068-08 | 1 – Red Blood Cells Leukocytes Reduced | Component preparation (product manufactured from an overweight unit of Whole Blood) | \$4,000 | \$4,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|-------------------------|--|---------------|--|---|--|-------------------------|
| Great Lakes/ 1873033 | (b) (4) | B-1579-6 | 3 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for increased risk of infection with hepatitis) | \$4,000 | \$32,000 |
| | | B-1582-6 | 2 – Cryoprecipitated AHF | | | |
| | | B-1585-6 | 2 – Plasma Frozen Cryoprecipitate Reduced | | | |
| | | B-1586-6 | 1 – Recovered Plasma | | | |
| Great Lakes/ 1873033 | (b) (4) | B-0566-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$5,000 |
| Great Lakes/ 1873033 | (b) (4) | B-1329-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Great Lakes/ 1873033 | (b) (4) | B-1331-08 | 1 – Fresh Frozen Plasma | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |
| | | B-1332-08 | 1 – Red Blood Cells Leukocytes Reduced | | | |
| Great Lakes/ 1873033 | (b) (4) | B-1333-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Great Lakes/ 1873033 | (b) (4) | B-1335-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Great Lakes/ 1873033 | (b) (4) | B-1358-08 | 2 – Red Blood Cells (Apheresis) Leukocytes Reduced | Component preparation (failure to perform required product quality control testing) | \$4,000 | \$8,000 |
| Great Lakes/ 1873033 | (b) (4) | B-1477-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Great Lakes/ 1873033 | (b) (4) | B-1695-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Great Lakes/ 1873033 | (b) (4) | B-1697-08 | 2 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|---------------------------------|---|----------------------|--|---|---|---------------------------------|
| Greater Alleghenies/ 2573016 | (b) (4) | B-0785-6 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (BDR question related to CJD was unanswered) | \$4,000 | \$4,000 |
| Greater Alleghenies/ 2573016 | (b) (4) | B-0805-6 | 1 – Red Blood Cells Leukocytes Reduced | Failure to control suspect blood component(s) (inappropriate release of blood components that should have been discarded) | \$5,000 | \$10,000 |
| | | B-0806-6 | 1 – Cryoprecipitated AHF | | | |
| Greater Alleghenies/ 2573016 | (b) (4) | B-1640-6 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered) | \$4,000 | \$4,000 |
| Greater Alleghenies/ 2573016 | (b) (4) | B-1787-6 | 1 – Red Blood Cells (Apheresis) Leukocytes Reduced | Collection (sterility may have been compromised) | \$5,000 | \$5,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|---|--|---------------|--|--|--|-------------------------|
| Greater Alleghenies/ 2573016 | (b) (4) | B-0285-7 | 1 – Platelets Pheresis Leukocytes Reduced | Failure to control suspect blood component(s) (supervisory review did not identify that the products failed the pH requirement) | \$5,000 | \$10,000 |
| | | B-0286-7 | 1 – Platelets Pheresis Leukocytes Reduced Irradiated | | | |
| Greater Alleghenies/ 2573016 | (b) (4) | B-0255-08 | 2 – Red Blood Cells (Apheresis) Leukocytes Reduced | Quality control and distribution (failure to perform QC on the pheresis machine) | \$4,000 | \$8,000 |
| Greater Alleghenies/ 2573016 | (b) (4) | B-0361-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |
| | | B-0362-08 | 1 – Platelets Leukocytes Reduced | | | |
| Greater Alleghenies/ 2573016 | (b) (4) | B-0398-08 | 4 – Red Blood Cells (Apheresis) Leukocytes Reduced | Quality control and distribution (failure to perform quality control testing on product) | \$4,000 | \$16,000 |
| Greater Alleghenies/ 2573016 | (b) (4) | B-1440-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |
| | | B-1441-08 | 1 – Cryoprecipitated AHF | | | |
| Greater Alleghenies/ 2573016 | (b) (4) | B-1765-08 | 3 – Platelets Pheresis Leukocytes Reduced | Quality control and distribution (failure to perform platelet count) | \$4,000 | \$12,000 |
| Greater Chesapeake and Potomac/ 1173011 | (b) (4) | B-1707-6 | 2 – Platelets Pheresis Leukocytes Reduced | Component preparation (plateletpheresis product did not meet specification for platelet yield) | \$4,000 | \$8,000 |
| Greater Chesapeake and Potomac/ 1173011 | (b) (4) | B-0002-7 | 1 – Platelets Pheresis Leukocytes Reduced | Component preparation (product had insufficient plasma to support the platelet yield and therefore did not meet specification) | \$4,000 | \$4,000 |
| Greater Chesapeake and Potomac/ 1173011 | (b) (4) | B-0006-7 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for residence in a malarial risk area) | \$4,000 | \$4,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|---|--|---------------|--|--|--|-------------------------|
| Greater Chesapeake and Potomac/ 1173011 | (b) (4) | B-0007-7 | 1 – Platelets Pheresis Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$4,000 | \$4,000 |
| Greater Chesapeake and Potomac/ 1173011 | (b) (4) | B-0012-7 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to assure that donor met acceptance criteria for hematocrit & body temperature) | \$3,000 | \$3,000 |
| Greater Chesapeake and Potomac/ 1173011 | (b) (4) | B-0020-7 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for medication use) | \$2,000 | \$4,000 |
| | | B-0021-7 | 1 – Platelets | | | |
| Greater Chesapeake and Potomac/ 1173011 | (b) (4) | B-0026-7 | 138 – Platelets Pheresis | Component preparation (plateletpheresis product did not meet specification for platelet yield) | \$4,000 for each of 100 blood components | \$400,000 |
| | | B-0027-7 | 25 – Platelets Pheresis Irradiated | | | |
| Greater Chesapeake and Potomac/ 1173011 | (b) (4) | B-1438-07 | 3 – Platelets Pheresis Leukocytes Reduced | Quality control and distribution (blood products were collected on equipment that was not validated) | \$4,000 | \$12,000 |
| Greater Chesapeake and Potomac/ 1173011 | (b) (4) | B-1439-07 | 2 – Platelets Pheresis Leukocytes Reduced | Quality control and distribution (blood products were collected on equipment that was not validated) | \$4,000 | \$8,000 |
| Greater Chesapeake and Potomac/ 1173011 | (b) (4) | B-1526-07 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Greater Chesapeake and Potomac/ 1173011 | (b) (4) | B-0754-08 | 1 – Red Blood Cells (Apheresis) Leukocytes Reduced | Quality control and distribution (failure to test for White Blood Cell count; product mislabeled) | \$4,000 | \$4,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|---|--|---------------|--|--|--|-------------------------|
| Greater Chesapeake and Potomac/ 1173011 | (b) (4) | B-0755-08 | 1 – Platelets Pheresis Leukocytes Reduced | Failure to control suspect blood component(s) (failure to quarantine the product due to potential contamination) | \$5,000 | \$5,000 |
| Greater Ozark- Arkansas/ 2372998 | (b) (4) | B-0049-08 | 1 – Red Blood Cells Leukocytes Reduced | Testing (failure to perform anti-HIV 1/2 testing correctly) | \$5,000 | \$5,000 |
| Greater Ozark- Arkansas/ 2372998 | (b) (4) | B-0221-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Greater Ozark- Arkansas/ 2372998 | (b) (4) | B-0424-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Gulf Coast/1073005 | (b) (4) | B-1234-07 | 1 – Red Blood Cells Leukocytes Reduced | Failure to control suspect blood component(s) (release of blood component from a donor who was previously incarcerated) | \$5,000 | \$10,000 |
| | | B-1235-07 | 1 - Recovered Plasma | | | |
| Heart of America/ 1473043 | (b) (4) | B-0802-6 | 2 – Platelets Pheresis Leukocytes Reduced | Collection (products collected using apheresis kits that had exceed the acceptable time period for use) | \$4,000 | \$8,000 |
| Heart of America/ 1473043 | (b) (4) | B-0844-6 | 1 - Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$4,000 | \$8,000 |
| | | B-0845-6 | 1 - Platelets Pheresis Leukocytes Reduced | | | |
| Heart of America/ 1473043 | (b) (4) | B-0950-6 | 1 - Platelets Pheresis Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$4,000 | \$4,000 |
| Heart of America/ 1473043 | (b) (4) | B-1144-6 | 1 - Red Blood Cells Leukocytes Reduced | Collection (inadequate arm prep; sterility may have been compromised) | \$5,000 | \$5,000 |
| Heart of America/ 1473043 | (b) (4) | B-1730-6 | 1 - Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|------------------------------|--|---------------|--|--|--|-------------------------|
| | | B-1731-6 | 1 – Plasma Frozen | | | |
| Heart of America/ 1473043 | (b) (4) | B-0182-7 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |
| | | B-0183-7 | 1 – Fresh Frozen Plasma | | | |
| Heart of America/ 1473043 | (b) (4) | B-0671-07 | 3 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$15,000 |
| Heart of America/ 1473043 | (b) (4) | B-1308-07 | 1 – Platelets Pheresis Leukocytes Reduced | Collection (products collected using apheresis kits that had exceed the acceptable time period for use) | \$4,000 | \$4,000 |
| Heart of America/ 1473043 | (b) (4) | B-1573-07 | 10 – Cryoprecipitated AHF | Component preparation (failure to freeze blood components within the required one hour following manufacture) | \$4,000 | \$40,000 |
| Heart of America/ 1473043 | (b) (4) | B-0087-08 | 1 – Platelets Pheresis Leukocytes Reduced Irradiated | Component preparation (irradiation not performed in accordance with specifications) | \$4,000 | \$4,000 |
| Heart of America/ 1473043 | (b) (4) | B-0089-08 | 1 – Red Blood Cells Leukocytes Reduced Irradiated | Component preparation (irradiation not performed in accordance with specifications) | \$4,000 | \$4,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|------------------------------|--|---------------|---|---|--|-------------------------|
| Heart of America/ 1473043 | (b) (4) | B-0268-08 | 118 – Cryoprecipitated AHF | Collection (inadequate arm prep; sterility may have been compromised) | \$5,000 for each of 100 blood components | \$500,000 |
| | | B-0269-08 | 84 – Red Blood Cells | | | |
| | | B-0270-08 | 229 – Red Blood Cells Leukocytes Reduced | | | |
| | | B-0271-08 | 17 – Plasma Frozen | | | |
| | | B-0272-08 | 8 – Red Blood Cells Leukocytes Reduced Irradiated | | | |
| | | B-0273-08 | 71 – Fresh Frozen Plasma | | | |
| Heart of America/ 1473043 | (b) (4) | B-1387-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel in a CJD risk area) | \$5,000 | \$20,000 |
| | | B-1388-08 | 1 – Frozen Plasma | | | |
| | | B-1389-08 | 2 – Recovered Plasma | | | |
| Heart of America/ 1473043 | (b) (4) | B-1558-08 | 2 – Red Blood Cells | Collection (inadequate arm prep; sterility may have been compromised) | \$5,000 | \$70,000 |
| | | B-1559-08 | 9 – Red Blood Cells Leukocytes Reduced | | | |
| | | B-1560-08 | 1 – Cryoprecipitated AHF | | | |
| | | B-1561-08 | 1 – Cryoprecipitated AHF, Pooled | | | |
| | | B-1562-08 | 1 – Frozen Plasma | | | |
| Heart of America/ 1473043 | (b) (4) | B-1973-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Heart of America/ 1473043 | (b) (4) | B-1974-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |
| | | B-1975-08 | 1 – Fresh Frozen Plasma | | | |
| Indiana-Ohio/ 1873031 | (b) (4) | B-0708-07 | 1 – Platelets Pheresis Leukocytes Reduced | Component preparation (irradiation not performed in accordance with specifications) | \$4,000 | \$4,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|-----------------------------|--|---------------|--|---|--|-------------------------|
| Indiana-Ohio/ 1873031 | (b) (4) | B-2050-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Lewis and Clark/ 3072990 | (b) (4) | B-0979-07 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to follow up on medications taken by donor) | \$2,000 | \$2,000 |
| Mid Atlantic/ 1173024 | (b) (4) | B-0244-7 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to perform a hematocrit after donor failed hemoglobin acceptance criteria) | \$4,000 | \$4,000 |
| Mid Atlantic/ 1173024 | (b) (4) | B-1388-07 | 1 – Red Blood Cells | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Mid Atlantic/ 1173024 | (b) (4) | B-1433-07 | 1 – Red Blood Cells Leukocytes Reduced | Collection (inadequate arm prep; sterility may have been compromised) | \$5,000 | \$5,000 |
| Mid Atlantic/ 1173024 | (b) (4) | B-1427-08 | 14 – Red Blood Cells Leukocytes Reduced | Collection (sterility may have been compromised) | \$5,000 | \$70,000 |
| Mid Atlantic/ 1173024 | (b) (4) | B-1513-08 | 1 – Red Blood Cells | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Mid Atlantic/ 1173024 | (b) (4) | B-1580-08 | 1 – Red Blood Cells Leukocytes Reduced | Collection (inadequate arm prep; sterility may have been compromised) | \$5,000 | \$5,000 |
| New England/ 1270026 | (b) (4) | B-1801-6 | 1 – Platelets Pheresis Leukocytes Reduced | Component preparation (platelet yield too high for storage in a single bag) | \$4,000 | \$4,000 |
| New England/ 1270026 | (b) (4) | B-1612-6 | 2 – Red Blood Cells Leukocytes Reduced | Collection (sterility may have been compromised) | \$5,000 | \$15,000 |
| | | B-1613-6 | 1 – Plasma Frozen | | | |
| New England/ 1270026 | (b) (4) | B-0753-07 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for residence in a malarial risk area) | \$5,000 | \$5,000 |
| New England/ 1270026 | (b) (4) | B-0786-07 | 1 – Platelets Pheresis Leukocytes Reduced | Collection (inadequate arm prep; sterility may have been compromised) | \$5,000 | \$10,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|-------------------------|--|---------------|--|---|--|-------------------------|
| | | B-0787-07 | 1 – Platelets Pheresis Leukocytes Reduced Irradiated | | | |
| New England/ 1270026 | (b) (4) | B-1310-7 | 1 – Platelets Pheresis Leukocytes Reduced | Component preparation (plateletpheresis product did not meet specification for platelet yield) | \$4,000 | \$4,000 |
| New England/ 1270026 | (b) (4) | B-1334-07 | 1 – Red Blood Cells | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$5,000 |
| New England/ 1270026 | (b) (4) | B-1370-07 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$5,000 |
| New England/ 1270026 | (b) (4) | B-0635-08 | 3 – Red Blood Cells | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$55,000 |
| | | B-0636-08 | 2 – Fresh Frozen Plasma | | | |
| | | B-0637-08 | 5 – Red Blood Cells Leukocytes Reduced | | | |
| | | B-0638-08 | 1 – Plasma Frozen | | | |
| New England/ 1270026 | (b) (4) | B-0701-08 | 3 – Red Blood Cells | Failure to control suspect blood component(s) (donor was not properly deferred after testing anti-HIV reactive on a previous donation) | \$5,000 | \$110,000 |
| | | B-0702-08 | 8 – Red Blood Cells Leukocytes Reduced | | | |
| | | B-0703-08 | 1 – Red Blood Cells Irradiated | | | |
| | | B-0704-08 | 2 – Red Blood Cells Leukocytes Reduced Irradiated | | | |
| | | B-0705-08 | 4 – Platelets | | | |
| | | B-0706-08 | 3 – Fresh Frozen Plasma | | | |
| | | B-0707-08 | 1 – Plasma Frozen | | | |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|-------------------------|--|---------------|---|--|--|-------------------------|
| New England/ 1270026 | (b) (4) | B-0716-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$5,000 |
| New England/ 1270026 | (b) (4) | B-0725-08 | 2 – Red Blood Cells (Apheresis) | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$30,000 |
| | | B-0726-08 | 4 – Platelets Pheresis Leukocytes Reduced | | | |
| New England/ 1270026 | (b) (4) | B-0742-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for residence in a malarial risk area) | \$5,000 | \$10,000 |
| | | B-0743-08 | 1 – Red Blood Cells Leukocytes Reduced Irradiated | | | |
| New England/ 1270026 | (b) (4) | B-0785-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| New England/ 1270026 | (b) (4) | B-0808-08 | 1 – Red Blood Cells Leukocytes Reduced | Failure to control suspect blood component(s) (failure to quarantine components from a donor with a questionable donation status) | \$5,000 | \$5,000 |
| New England/ 1270026 | (b) (4) | B-0824-08 | 2 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |
| New England/ 1270026 | (b) (4) | B-0843-08 | 3 – Platelets Pheresis Leukocytes Reduced | Quality control and distribution (failure to test for White Blood Cell count; product mislabeled) | \$4,000 | \$12,000 |
| New England/ 1270026 | (b) (4) | B-0917-08 | 2 – Red Blood Cells | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$50,000 |
| | | B-0918-08 | 5 – Red Blood Cells Leukocytes Reduced | | | |
| | | B-0919-08 | 2 – Plasma Frozen | | | |
| | | B-0920-08 | 1 – Red Blood Cells Leukocytes Reduced Irradiated | | | |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|---------------------------|--|---------------|--|--|--|-------------------------|
| New England/ 1270026 | (b) (4) | B-0926-08 | 2 – Platelets Pheresis Leukocytes Reduced Irradiated | Failure to control suspect blood component(s) (product was not discarded after discovery that it should have been discarded based on platelet yield) | \$5,000 | \$20,000 |
| | | B-0927-08 | 2 – Platelets Pheresis Leukocytes Reduced | | | |
| New England/ 1270026 | (b) (4) | B-1081-08 | 2 – Red Blood Cells | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$35,000 |
| | | B-1082-08 | 3 – Red Blood Cells Leukocytes Reduced | | | |
| | | B-1083-08 | 2 – Fresh Frozen Plasma | | | |
| New England/ 1270026 | (b) (4) | B-1087-08 | 1 – Recovered Plasma | Donor eligibility (failure to defer donor for travel in a CJD risk area) | \$5,000 | \$5,000 |
| New England/ 1270026 | (b) (4) | B-1109-08 | 15 – Platelets Pheresis Leukocytes Reduced | Quality control and distribution (failure to perform quality control testing on product) | \$4,000 | \$60,000 |
| New England/ 1270026 | (b) (4) | B-1188-08 | 1 – Red Blood Cells | Failure to control suspect blood component(s) (failure to quarantine component from an overweight unit) | \$5,000 | \$5,000 |
| New England/ 1270026 | (b) (4) | B-2037-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| New England/ 1270026 | (b) (4) | B-2042-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| North Central/ 2173038 | (b) (4) | B-1596-07 | 6 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor who reported a positive test result for hepatitis) | \$5,000 | \$75,000 |
| | | B-1597-07 | 4 – Platelets Leukocytes Reduced | | | |
| | | B-1599-07 | 3 – Recovered Plasma | | | |
| | | B-1598-07 | 2 – Frozen Plasma | | | |
| North Central/ 2173038 | (b) (4) | B-0059-08 | 9 – Red Blood Cells (Apheresis) Leukocytes Reduced | Failure to control suspect blood component(s) (sterility may have been compromised) | \$5,000 | \$45,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|---------------------------|--|---------------|--|---|--|-------------------------|
| North Central/ 2173038 | (b) (4) | B-1045-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$4,000 | \$4,000 |
| North Central/ 2173038 | (b) (4) | B-1458-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$4,000 | \$4,000 |
| North Central/ 2173038 | (b) (4) | B-1463-08 | 1 – Red Blood Cells | Donor eligibility (failure to defer donor for residence in a malarial risk area) | \$4,000 | \$4,000 |
| North Central/ 2173038 | (b) (4) | B-1495-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for reporting history of hepatitis) | \$4,000 | \$8,000 |
| | | B-1496-08 | 1 – Recovered Plasma | | | |
| North Central/ 2173038 | (b) (4) | B-1508-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for residence in a malarial risk area) | \$4,000 | \$8,000 |
| | | B-1509-08 | 1 – Platelets Leukocytes Reduced | | | |
| North Central/ 2173038 | (b) (4) | B-1514-08 | 1 – Platelets Pheresis Leukocytes Reduced Irradiated | Quality control and distribution (failure to test for White Blood Cell count; product mislabeled) | \$4,000 | \$4,000 |
| Northeastern/ 2573018 | (b) (4) | B-1320-07 | 4 – Red Blood Cells Leukocytes Reduced | Collection (hematocrit quality control was not acceptable) | \$4,000 | \$16,000 |
| Northeastern/ 2573018 | (b) (4) | B-0129-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$5,000 |
| Northeastern/ 2573018 | (b) (4) | B-0248-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Northeastern/ 2573018 | (b) (4) | B-1091-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$5,000 |
| Northeastern/ 2573018 | (b) (4) | B-1424-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$5,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|------------------------------------|---|----------------------|---|---|---|---------------------------------|
| Northeastern/ 2573018 | (b) (4) | B-1432-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Northeastern/ 2573018 | (b) (4) | B-1625-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Northeastern/ 2573018 | (b) (4) | B-1628-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Northeastern/ 2573018 | (b) (4) | B-1678-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Northern California/ 2971430 | (b) (4) | B-1601-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$4,000 | \$4,000 |
| Northern California/ 2971430 | (b) (4) | B-1602-08 | 2 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$4,000 | \$8,000 |
| Northern California/ 2971430 | (b) (4) | B-1603-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$4,000 | \$4,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|---------------------------|--|---------------|--|--|--|-------------------------|
| Northern Ohio/ 1573019 | (b) (4) | B-0235-7 | 10 – Platelets Pheresis Leukocytes Reduced | Storage/shipping (blood components may have been shipped at unacceptable temperatures) | \$4,000 | \$52,000 |
| | | B-0236-7 | 3 – Platelets Pheresis Leukocytes Reduced Irradiated | | | |
| Penn Jersey/ 2573021 | (b) (4) | B-1644-6 | 2 – Platelets Pheresis Leukocytes Reduced | Donor eligibility (BDR question related to CJD was unanswered) | \$4,000 | \$8,000 |
| Penn Jersey/ 2573021 | (b) (4) | B-1676-6 | 1 – Platelets Pheresis Leukocytes Reduced | Failure to control suspect blood component(s) (product distributed prior to resolution of a quality control failure for platelet yield) | \$5,000 | \$5,000 |
| Penn Jersey/ 2573021 | (b) (4) | B-1717-6 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$4,000 | \$8,000 |
| | | B-1718-6 | 1 – Platelets Leukocytes Reduced | | | |
| Penn Jersey/ 2573021 | (b) (4) | B-0139-7 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$10,000 |
| | | B-0140-7 | 1 – Platelets Leukocytes Reduced | | | |
| Penn Jersey/ 2573021 | (b) (4) | B-0321-7 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$5,000 |
| Penn Jersey/ 2573021 | (b) (4) | B-0352-7 | 2 - Red Blood Cells | Collection (inadequate arm prep; sterility may have been compromised) | \$5,000 | \$325,000 |
| | | B-0353-7 | 35 – Red Blood Cells Leukocytes Reduced | | | |
| | | B-0354-7 | 17 – Platelets Leukocytes Reduced | | | |
| | | B-0355-7 | 11 – Fresh Frozen Plasma | | | |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|-------------------------|---|----------------------|---|--|---|---------------------------------|
| Penn Jersey/ 2573021 | (b) (4) | B-0550-07 | 1 – Red Blood Cells Leukocytes Reduced Irradiated | Donor eligibility (BDR questions unanswered) | \$4,000 | \$4,000 |
| Penn Jersey/ 2573021 | (b) (4) | B-0756-07 | 141 – Red Blood Cells Leukocytes Reduced | Collection (inadequate arm prep; sterility may have been compromised) | \$5,000 for each of 100 blood components | \$500,000 |
| | | B-0757-07 | 5 – Red Blood Cells | | | |
| | | B-0758-07 | 2 – Red Blood Cells Leukocytes Reduced Irradiated | | | |
| | | B-0759-07 | 13 – Whole Blood | | | |
| | | B-0760-07 | 51 – Cryoprecipitated AHF | | | |
| | | B-0761-07 | 8 – Platelets Leukocytes Reduced | | | |
| | | B-0762-07 | 123 – Fresh Frozen Plasma | | | |
| | | B-0763-07 | 29 – Plasma Frozen Within 24 Hours | | | |
| | | B-0764-07 | 7 – Plasma Cryoprecipitate Reduced | | | |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|-------------------------|--|---------------|---|--|--|-------------------------|
| Penn Jersey/ 2573021 | (b) (4) | B-0876-07 | 42 – Red Blood Cells | Collection (inadequate arm prep; sterility may have been compromised) | \$5,000 for each of 100 blood components | \$500,000 |
| | | B-0877-07 | 1 – Red Blood Cells (Apheresis) | | | |
| | | B-0878-07 | 30 – Red Blood Cells Leukocytes Reduced | | | |
| | | B-0879-07 | 1 – Red Blood Cells Leukocytes Reduced Irradiated | | | |
| | | B-0880-07 | 2 – Platelets Leukocytes Reduced | | | |
| | | B-0881-07 | 8 – Platelets Pheresis Leukocytes Reduced | | | |
| | | B-0882-07 | 434 – Fresh Frozen Plasma | | | |
| | | B-0883-07 | 85 – Cryoprecipitated AHF | | | |
| | | B-0884-07 | 42 – Plasma Frozen Within 24 Hours | | | |
| | | B-0885-07 | 25 - Plasma Frozen Cryoprecipitate Reduced | | | |
| Penn Jersey/ 2573021 | (b) (4) | B-0905-07 | 1600 – Platelets Leukocytes Reduced | Quality control and distribution (product with unacceptable product quality control) | \$4,000 for each of 100 blood components | \$400,000 |
| | | B-0906-07 | 55 – Platelets Leukocytes Reduced Irradiated | | | |
| Penn Jersey/ 2573021 | (b) (4) | B-1257-07 | 893 – Platelets Leukocytes Reduced | Component preparation (plateletpheresis product did not meet specification for platelet yield) | \$4,000 for each of 100 blood components | \$400,000 |
| Penn Jersey/ 2573021 | (b) (4) | B-1298-07 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$5,000 |
| Penn Jersey/ 2573021 | (b) (4) | B-1363-07 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor who was previous HIV positive) | \$5,000 | \$15,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|-------------------------|--|---------------|--|---|--|-------------------------|
| | | B-1364-07 | 1 – Cryoprecipitated AHF | | | |
| | | B-1365-07 | 1 – Plasma Frozen Cryoprecipitate Reduced | | | |
| Penn Jersey/ 2573021 | (b) (4) | B-0348-08 | 1 – Fresh Frozen Plasma | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |
| | | B-0349-08 | 1 – Red Blood Cells Leukocytes Reduced | | | |
| Penn Jersey/ 2573021 | (b) (4) | B-0350-08 | 1 – Cryoprecipitated AHF | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$20,000 |
| | | B-0351-08 | 2 – Red Blood Cells Leukocytes Reduced | | | |
| | | B-0352-08 | 1 – Platelets Leukocytes Reduced | | | |
| Penn Jersey/ 2573021 | (b) (4) | B-0354-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor who was previous HIV positive) | \$5,000 | \$10,000 |
| | | B-0355-08 | 1 – Platelets Leukocytes Reduced | | | |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|-------------------------|--|---------------|--|---|--|-------------------------|
| Penn Jersey/ 2573021 | (b) (4) | B-0357-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |
| | | B-0358-08 | 1 – Platelets Leukocytes Reduced | | | |
| Penn Jersey/ 2573021 | (b) (4) | B-0400-08 | 2 – Red Blood Cells Leukocytes Reduced Irradiated | Component preparation (irradiation not performed in accordance with specifications) | \$4,000 | \$8,000 |
| Penn Jersey/ 2573021 | (b) (4) | B-0406-08 | 2 – Red Blood Cells (Apheresis) Leukocytes Reduced | Quality control and distribution (failure to perform quality control testing on product) | \$4,000 | \$8,000 |
| Penn Jersey/ 2573021 | (b) (4) | B-0487-08 | 1 – Cryoprecipitated AHF | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$15,000 |
| | | B-0488-08 | 1 – Red Blood Cells Leukocytes Reduced | | | |
| | | B-0489-08 | 1 – Plasma Cryoprecipitate Reduced | | | |
| Penn Jersey/ 2573021 | (b) (4) | B-0610-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |
| | | B-0611-08 | 1 – Fresh Frozen Plasma | | | |
| Penn Jersey/ 2573021 | (b) (4) | B-0661-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Penn Jersey/ 2573021 | (b) (4) | B-0679-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Penn Jersey/ 2573021 | (b) (4) | B-0681-08 | 1 – Fresh Frozen Plasma | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$15,000 |
| | | B-0682-08 | 1 – Red Blood Cells Leukocytes Reduced | | | |
| | | B-0683-08 | 1 – Platelets Leukocytes Reduced | | | |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|-------------------------|--|---------------|---|---|--|-------------------------|
| Penn Jersey/ 2573021 | (b) (4) | B-1004-08 | 108 – Fresh Frozen Plasma | Collection (inadequate arm prep; sterility may have been compromised) | \$5,000 for each of 100 blood components | \$500,000 |
| | | B-1005-08 | 192 – Red Blood Cells Leukocytes Reduced | | | |
| | | B-1006-08 | 80 – Platelets Leukocytes Reduced | | | |
| | | B-1007-08 | 7 – Red Blood Cells Leukocytes Reduced Irradiated | | | |
| | | B-1008-08 | 7 – Red Blood Cells | | | |
| | | B-1009-08 | 4 – Whole Blood CPD | | | |
| | | B-1010-08 | 6 – Whole Blood CPDA-1 | | | |
| | | B-1011-08 | 44 – Cryoprecipitated AHF | | | |
| | | B-1012-08 | 12 – Platelets Pooled Leukocytes Reduced | | | |
| | | B-1013-08 | 5 – Plasma Frozen Within 24 Hours | | | |
| | | B-1014-08 | 1 – Plasma Cryoprecipitate Reduced | | | |
| Penn Jersey/ 2573021 | (b) (4) | B-1156-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |
| | | B-1157-08 | 1 – Platelets Leukocytes Reduced | | | |
| Penn Jersey/ 2573021 | (b) (4) | B-1636-08 | 2 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$15,000 |
| | | B-1637-08 | 1 – Cryoprecipitated AHF | | | |
| Penn Jersey/ 2573021 | (b) (4) | B-1674-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$15,000 |
| | | B-1675-08 | 1 – Fresh Frozen Plasma | | | |
| | | B-1676-08 | 1 – Platelets Leukocytes Reduced | | | |
| Penn Jersey/ 2573021 | (b) (4) | B-2043-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |
| | | B-2044-08 | 1 – Plasma Frozen | | | |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|------------------------|--|---------------|---|---|--|-------------------------|
| Puerto Rico/2675945 | (b) (4) | B-1873-08 | 51 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$4,000 | \$208,000 |
| | | B-1874-08 | 1 – Platelets Pheresis Leukocytes Reduced | | | |
| Puerto Rico/2675945 | (b) (4) | B-1916-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (BDR question related to HIV high risk behavior was unanswered) | \$5,000 | \$5,000 |
| Puerto Rico/2675945 | (b) (4) | B-1917-08 | 1 – Recovered Plasma | Donor eligibility (BDR question related to exposure to another person's blood was unanswered) | \$4,000 | \$4,000 |
| South Carolina/1073009 | (b) (4) | B-0096-08 | 1 – Fresh Frozen Plasma | Donor eligibility (inadequate donor screening related to gender-specific questions and travel in a CJD risk area) | \$4,000 | \$12,000 |
| | | B-0097-08 | 2 – Red Blood Cells Leukocytes Reduced | | | |
| South Carolina/1073009 | (b) (4) | B-0469-08 | 1 – Red Blood Cells Leukocytes Reduced Irradiated | Storage/shipping (product may have been out of controlled storage for greater than 30 minutes) | \$4,000 | \$4,000 |
| Southeastern/1873044 | (b) (4) | B-1545-08 | 2 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered) | \$5,000 | \$10,000 |
| Southeastern/1873044 | (b) (4) | B-1722-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel in malarial risk area) | \$5,000 | \$10,000 |
| | | B-1723-08 | 1 – Platelets Leukocytes Reduced | | | |
| Southern/1073000 | (b) (4) | B-1682-6 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (donor's hemoglobin was unacceptable and the hematocrit determination was not performed) | \$4,000 | \$4,000 |
| Southern/1073000 | (b) (4) | B-0066-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered) | \$5,000 | \$10,000 |
| | | B-0067-08 | 1 – Plasma Frozen | | | |
| Southern/1073000 | (b) (4) | B-0085-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered) | \$5,000 | \$5,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|-----------------------|--|---------------|--|---|--|-------------------------|
| Southern/ 1073000 | (b) (4) | B-0280-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$5,000 |
| Southern/ 1073000 | (b) (4) | B-0306-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |
| | | B-0307-08 | 1 – Plasma Frozen | | | |
| Southern/ 1073000 | (b) (4) | B-0308-08 | 5 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$25,000 |
| Southern/ 1073000 | (b) (4) | B-0325-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Southern/ 1073000 | (b) (4) | B-0570-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Southern/ 1073000 | (b) (4) | B-0573-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |
| | | B-0574-08 | 1 – Plasma Frozen | | | |
| Southern/ 1073000 | (b) (4) | B-1325-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (inadequate donor screening) | \$5,000 | \$5,000 |
| Southwest/ 1673040 | (b) (4) | B-0186-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Southwest/ 1673040 | (b) (4) | B-0410-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$5,000 |
| Southwest/ 1673040 | (b) (4) | B-0419-08 | 1 – Platelets Pheresis Leukocytes Reduced Irradiated | Collection (sterility may have been compromised) | \$5,000 | \$5,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|-----------------------|--|---------------|---|---|--|-------------------------|
| Southwest/ 1673040 | (b) (4) | B-0516-08 | 93 – Red Blood Cells Leukocytes Reduced | Collection (sterility may have been compromised and failure to follow manufacturer's instructions) | \$5,000 for each of 100 blood components | \$500,000 |
| | | B-0517-08 | 72 – Fresh Frozen Plasma | | | |
| | | B-0518-08 | 53 – Platelets Leukocytes Reduced | | | |
| | | B-0519-08 | 1 – Red Blood Cells Leukocytes Reduced Irradiated | | | |
| Southwest/ 1673040 | (b) (4) | B-0520-08 | 62 – Red Blood Cells Leukocytes Reduced | Collection (sterility may have been compromised and failure to follow manufacturer's instructions) | \$5,000 for each of 100 blood components | \$500,000 |
| | | B-0521-08 | 40 – Fresh Frozen Plasma | | | |
| | | B-0522-08 | 31 – Platelets Leukocytes Reduced | | | |
| | | B-0523-08 | 5 – Red Blood Cells Leukocytes Reduced Irradiated | | | |
| Southwest/ 1673040 | (b) (4) | B-0524-08 | 1 – Platelets Pheresis Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$5,000 |
| Southwest/ 1673040 | (b) (4) | B-0526-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$4,000 | \$4,000 |
| Southwest/ 1673040 | (b) (4) | B-0528-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$10,000 |
| | | B-0529-08 | 1 – Plasma Frozen | | | |
| Southwest/ 1673040 | (b) (4) | B-0553-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Southwest/ 1673040 | (b) (4) | B-0555-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Southwest/ 1673040 | (b) (4) | B-0557-08 | 1 – Platelets Pheresis Leukocytes Reduced | Component preparation (platelet yield too high for storage in a single bag) | \$4,000 | \$4,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|------------------------------|--|---------------|--|--|--|-------------------------|
| Southwest/ 1673040 | (b) (4) | B-0561-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Southwest/ 1673040 | (b) (4) | B-0590-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Southwest/ 1673040 | (b) (4) | B-0648-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Southwest/ 1673040 | (b) (4) | B-0787-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$4,000 | \$4,000 |
| Southwest/ 1673040 | (b) (4) | B-1069-08 | 42 – Platelets Pheresis Leukocytes Reduced | Collection (products collecting using apheresis kits that had exceeded the acceptable time period for use) | \$4,000 | \$188,000 |
| | | B-1070-08 | 5 – Platelets Pheresis Leukocytes Reduced Irradiated | | | |
| Tennessee Valley/ 1073006 | (b) (4) | B-1449-07 | 2 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$10,000 |
| Tennessee Valley/ 1073006 | (b) (4) | B-1499-07 | 2 – Red Blood Cells (Apheresis) Leukocytes Reduced | Collection (products collected using apheresis kits that had exceed the acceptable time period for use) | \$4,000 | \$8,000 |
| Tennessee Valley/ 1073006 | (b) (4) | B-0176-08 | 1 – Platelets Leukocytes Reduced Irradiated | Collection (inadequate arm prep; sterility may have been compromised) | \$5,000 | \$5,000 |
| Tennessee Valley/ 1073006 | (b) (4) | B-0654-08 | 1 – Fresh Frozen Plasma | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$15,000 |
| | | B-0655-08 | 1 – Red Blood Cells Leukocytes Reduced | | | |
| | | B-0656-08 | 1 - Platelets Leukocytes Reduced | | | |
| Tennessee Valley/ 1073006 | (b) (4) | B-0722-08 | 4 – Red Blood Cells Leukocytes Reduced | Donor eligibility (failure to defer donor for travel to a malarial risk area) | \$5,000 | \$40,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|------------------------------|--|---------------|---|---|--|-------------------------|
| | | B-0723-08 | 4 – Platelets Leukocytes Reduced | | | |
| Tennessee Valley/ 1073006 | (b) (4) | B-0749-08 | 5 – Red Blood Cells Leukocytes Reduced | Collection (inadequate arm prep; sterility may have been compromised) | \$5,000 | \$25,000 |
| Tennessee Valley/ 1073006 | (b) (4) | B-0750-08 | 10 – Red Blood Cells Leukocytes Reduced | Collection (inadequate arm prep; sterility may have been compromised) | \$5,000 | \$110,000 |
| | | B-0751-08 | 11 – Platelets | | | |
| | | B-0752-08 | 1 – Fresh Frozen Plasma | | | |
| Tennessee Valley/ 1073006 | (b) (4) | B-0853-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |
| Tennessee Valley/ 1073006 | (b) (4) | B-1392-08 | 1 – Red Blood Cells Leukocytes Reduced | Failure to control suspect blood component(s) (inappropriate release of blood components that should have been discarded because donor was taking Coumadin) | \$5,000 | \$5,000 |
| Tennessee Valley/ 1073006 | (b) (4) | B-1398-08 | 1 – Red Blood Cells Leukocytes Reduced | Donor eligibility (incorrect gender assigned; incorrect BDR gender- specific questions were answered) | \$5,000 | \$5,000 |

| Region/FEI | BPDR Number or ARC Problem Report Number | Recall Number | Number of Recalled Products/Product Type | Reason for Recall | Penalty Amount Per Blood Component | Total Penalty Amount |
|------------------------------|--|---------------|---|---|--|-------------------------|
| Tennessee Valley/ 1073006 | (b) (4) | B-1412-08 | 1 – Fresh Frozen Plasma | Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered) | \$5,000 | \$10,000 |
| | | B-1413-08 | 1 – Red Blood Cells Leukocytes Reduced | | | |
| Tennessee Valley/ 1073006 | (b) (4) | B-1829-08 | 112 – Red Blood Cells Leukocytes Reduced | Collection (inadequate arm prep; sterility may have been compromised) | \$5,000 for each of 100 blood components | \$500,000 |
| | | B-1830-08 | 42 – Platelets Leukocytes Reduced | | | |
| | | B-1831-08 | 24 – Fresh Frozen Plasma | | | |
| Tennessee Valley/ 1073006 | (b) (4) | B-2032-08 | 1 – Red Blood Cells Leukocytes Reduced | Failure to control suspect blood component(s) (failure to quarantine component after discovery that donor had traveled to a malarial risk area) | \$5,000 | \$5,000 |
| Tennessee Valley/ 1073006 | (b) (4) | B-2064-08 | 1 – Fresh Frozen Plasma | Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered) | \$5,000 | \$25,000 |
| | | B-2065-08 | 2 – Red Blood Cells Leukocytes Reduced | | | |
| | | B-2066-08 | 2 – Platelets Leukocytes Reduced | | | |
| Tennessee Valley/ 1073006 | (b) (4) | B-2067-08 | 1 – Fresh Frozen Plasma | Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered) | \$5,000 | \$10,000 |
| | | B-2068-08 | 1 – Red Blood Cells Leukocytes Reduced | | | |
| Tennessee Valley/ 1073006 | (b) (4) | B-2070-08 | 1 – Fresh Frozen Plasma | Donor eligibility (incorrect gender assigned; incorrect BDR gender-specific questions were answered) | \$5,000 | \$20,000 |
| | | B-2071-08 | 3 – Red Blood Cells Leukocytes Reduced | | | |
| | | | | | | \$9,776,000 |